K011819

JUN 1 9 2001

510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: June 7, 2001

Applicant: Avanta Orthopaedics, Inc.
9369 Carroll Park Drive, Suite A
San Diego, CA 92121

Telephone: 858-452-8580
Fax: 858-452-9945
Contact: Louise M. Focht

Device Name:	Radial Head Implant
Device Trade Name:	Radial head implant
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	21 CFR § 888.3170
Product Code:	~~87~~ KWI
Original Predicate Device:	Swanson Titanium Radial Head Implant originally by Wright Medical which has been marketed since 1994.
Registration Number:	2030506
Owner Operator Number:	9001389

Device Description:

The radial head implant like the predicate device includes various sizes of implants and accessories including sizers. The implant allows for replacement of the proximal radial head.

Indications for Use:

Avanta Orthopaedics Radial Head implant is intended for replacement of the proximal end of the radius:

- Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and or proximal radio-ulnar joint with:
    - joint destruction or subluxation visible on x-ray
    - resistance to conservative treatment
- Primary replacement after fracture of the radial head
    - Symptomatic sequelae after radial head resection

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Comparison to the Original Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the Wright Medical Swanson Titanium Radial Head Implant.

Regulatory Class: II
Product Code: 87 KXE

Table 2. Comparison of Wright Medical and Avanta radial head

Item	*Avanta Product*	*Wright Medical Technologies*
Product Name	Radial Head Implant	Swanson Titanium Radial Head Implant
Use	Single use	Single use
Fixation	stem in intramedulary canal	stem in intramedulary canal
Constraint	non constrained	non constrained
Material	Co-Cr/CpTi.	Titanium
Sizes	3 sizes, 1, 2, 3	5 sizes 1, 1.5, 2, 2.5, 3
Indications for use	Avanta Orthopaedics Radial Head implant is intended for replacement of the proximal end of the radius: Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with : • joint destruction or subluxation visible on x-ray • resistance to conservative treatment Primary replacement after fracture of the radial head Symptomatic sequelae after radial head resection Revision following failed radial head arthroplasty	Swanson Titanium Radial Head implant is intended for replacement of the proximal end of the radius: Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with : • joint destruction or subluxation visible on x-ray • resistance to conservative treatment Primary replacement after fracture of the radial head Symptomatic sequelae after radial head resection Revision following failed radial head arthroplasty

Similarities of the Avanta Orthopaedics Radial Head Implant and the Wright Medical Technology, Inc. Radial Head Implant include; Both devices are intended for single use only; Both devices are intended for surgical implantation longer than 30 days; Both devices are placed into the intramedullary canal of the proximal end of the radius; Both devices are made of industry standard materials. No new materials are introduced in either product; Both devices are comparably sized; Both devices have the same indications for use.

Summary:

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2001

Ms. Louise Focht
Regulatory Affairs Department
Avanta Orthopaedics, Inc.
9369 A Carroll Park Drive
San Diego, California 92121

Re: K011819
Trade Name: Radial Head Implant
Regulation Number: 888.3170
Regulatory Class: II
Product Code: KWI
Dated: June 7, 2001
Received: June 11, 2001

Dear Ms. Focht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510 (k) Number (If Known): K011819
Device Name: Radial Head

Indications for Use:

Avanta Orthopaedics Radial Head implant is intended for replacement of the proximal end of the radius:

- Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and or proximal radio-ulnar joint with:
    - joint destruction or subluxation visible on x-ray
    - resistance to conservative treatment
- Primary replacement after fracture of the radial head
    - Symptomatic sequelae after radial head resection

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature] for

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011819

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)